CLAIMS

We Claim:

1. A system for manipulating a core body temperature of a mammal, the system comprising:

a chamber for enclosing a body portion of a mammal;

a seal in operative association with said chamber for sealing said chamber around said body portion and for inhibiting movement of said body portion relative to said chamber when the system is in operation;

a thermal energy exchange system in operative association with said chamber, wherein said thermal energy exchange system comprises an energy element assembly coupled to a flexible membrane assembly, wherein said flexible membrane assembly facilitates an exchange of energy between said energy element assembly and said body portion; and

a vacuum system operatively associated with said chamber while said thermal energy exchange system is in operation, wherein said vacuum system generates a sub-atmospheric pressure within said chamber.

2. The system of claim 1, wherein said body portion is one of an extremity, part of an extremity, a head, a neck, and a torso.

3. The system of claim 1, wherein said chamber comprises:

a base member;

a moveable member adapted to matingly engage said base member; and

a fastener adapted to maintain engagement of said base member with said moveable member.

4. The system of claim 1, wherein said chamber comprises:

a base member having a first distal end and a first sealing surface; and

a moveable member having a second distal end pivotally mounted to said first distal end and a second sealing surface which reciprocably contacts said first sealing surface to enclose said body portion within said chamber.

5. The system of claim 4, further comprising a fastener in operative association with said base member and said moveable member for securely engaging said moveable member with said base member during operation of the system.

6. The system of claim 4, said flexible membrane assembly comprising a first flexible membrane associated with an interior surface of said moveable member and a second flexible membrane associated with an interior surface of said base member, wherein said first flexible membrane and said second flexible membrane are each configured to enhance surface contact between said energy element and said body portion.

7. The system of claim 6, wherein said seal comprises:

a first cuff positioned at a proximate end of said interior surface of said moveable member; and

a second cuff positioned at a proximate end of said interior surface of said base member;

wherein said first cuff and said second cuff are configured to surround said body portion when said moveable member contacts said base member to enclose said body portion within said chamber.

8. The system of claim 7, wherein said seal further comprises:

a first bladder at least partially encased within said first cuff; and

a second bladder at least partially encased within said second cuff;

wherein said first bladder and said second bladder are configured to form a pneumatic seal around said body portion during operation of the system.

9. The system of claim 8, wherein said first bladder and said second bladder are operatively associated with a pressure system which provides positive pressure to expand said first bladder and said second bladder around said body portion during operation of the system.

10. The system of claim 6, wherein said energy element assembly further comprises:

a first energy element in association with said first flexible membrane; and

a second energy element in association with said second flexible membrane;

wherein said first energy element and said second energy element are adapted to enable an exchange of energy via said body portion between each of said first energy element and said second energy element and said thermal core of said mammal.

11. The system of claim 10, wherein each of said first energy element and said second energy element is further adapted to enhance surface contact with said body portion.

12. The system of claim 10, wherein said first energy element and said second energy element each comprises one of a heating element and a cooling element.

13. The system of claim 10, wherein said first energy element and said second energy element are each configured to maintain a surface temperature of from about 5°C to about 48 °C.

14. The system of claim 10, wherein said thermal energy exchange system further comprises at least one backing layer which is contiguous with at least one of said first energy element and said second energy element and contacts at least one of said first flexible membrane and said second flexible membrane.

15. The system of claim 14, wherein said at least one backing layer comprises an insulating material.

16. The system of claim 15, wherein said insulating material comprises a phase change material.

17. The system of claim 10, wherein said thermal energy exchange system further comprises:

a circulation pump;

a fluid reservoir in operative association with said circulation pump; and

a temperature regulator coupled to said fluid reservoir.

18. The system of claim 17, wherein each of said first energy element and said second energy element each comprises a perfusion pad which is configured to be perfused with a temperature-regulated fluid.

19. The system of claim 18, wherein said temperature-regulated fluid is a liquid.

20. The system of claim 19, wherein said liquid is water.

21. The system of claim 1, wherein said chamber comprises:

a hollow tubular housing having an entry port positioned at a proximate end of said hollow tubular housing;

wherein said flexible membrane assembly forms a continuous membrane within said hollow tubular housing and is adapted to envelop said body portion when said body portion is positioned within said chamber.

22. The system of claim 21, wherein said chamber further comprises an annular cuff in association with said entry port, said annular cuff adapted to surround said body portion when said body portion is positioned within said chamber.

23. The system of claim 22, wherein said seal further comprises a bladder at least partially encased within said annular cuff, wherein said bladder is configured to form a pneumatic seal around said body portion during operation of the system.

24. The system of claim 21, wherein said energy element assembly comprises an energy element that is adapted to enable an exchange of energy between said energy element and said thermal core of said mammal via said body portion.

25. The system of claim 24, wherein said energy element comprises one of a heating element and a cooling element.

26. The system of claim 24, wherein said energy element is configured to maintain a surface temperature of from about 5 °C to about 48 °C.

27. The system of claim 24, wherein said thermal energy exchange system further comprises a backing layer which is contiguous with said energy element and contacts said flexible membrane.

28. The system of claim 27, wherein said backing layer comprises an insulating material.

29. The system of claim 28, wherein said insulating material comprises a phase change material.

30. The system of claim 24, wherein said thermal energy exchange system further comprises:

a circulation pump;

a fluid reservoir in operative association with said circulation pump; and

a temperature regulator coupled to said fluid reservoir.

31. The system of claim 30, wherein said energy element comprises a perfusion pad which is configured to be perfused with said temperature-regulated fluid.

32. The system of claim 1, wherein said selected sub-atmospheric pressure is from about -10 mmHg to about -400 mmHg, relative to atmospheric pressure.

33. The system of claim 32, wherein said vacuum system alternates between generating said selected sub-atmospheric pressure and permitting a return to atmospheric pressure within said chamber during operation of the system.

34. The system of claim 1, further comprising a sleeve into which said body portion is inserted prior to placement within said chamber.

35. The system of claim 34, wherein said sleeve comprises a first layer which is attached to a second layer to form a pocket into which said body portion is placed.

36. The system of claim 35, wherein said first layer is transparent.

37. The system of claim 35, wherein at least one of said first layer and said second layer is impregnated with a silver compound.

38. The system of claim 35, wherein at least one of said first layer and said second layer is associated with an insulating material.

39. The system of claim 38, wherein said insulating material comprises a phase change material.

40. The system of claim 1, wherein said chamber comprises:

a base member having a first side and a first sealing surface; and

a moveable member having a second side pivotally mounted to said first side and a second sealing surface which reciprocably contacts said first sealing surface to enclose said body portion within said chamber.

41. The system of claim 40, further comprising a fastener in operative association with said base member and said moveable member for securely engaging said moveable member with said base member during operation of the system.

42. The system of claim 40, said flexible membrane assembly comprising a first flexible membrane associated with an interior surface of said moveable member and a second flexible membrane associated with an interior surface of said base member, wherein said first flexible membrane and said second flexible membrane are each configured to enhance surface contact between said energy element and said body portion.

43. The system of claim 42, wherein said seal comprises:

a first cuff positioned at a proximate end of said interior surface of said moveable member;

a second cuff positioned at a proximate end of said interior surface of said base member;

a third cuff positioned at a distal end of said interior surface of said moveable member; and

a fourth cuff positioned at a distal end of said interior surface of said base member;

wherein said first and second cuffs are configured to form a first collar and said third and fourth cuffs are configured to form a second collar around said body portion when said moveable member contacts said base member, such that said body portion is enclosed within said chamber.

44. The system of claim 43, wherein said seal further comprises:

a first bladder at least partially encased within said first cuff;

a second bladder at least partially encased within said second cuff;

a third bladder at least partially encased within said third cuff; and

a fourth bladder at least partially encased within said fourth cuff;

wherein said first bladder and said second bladder form a proximate bladder pair, said third bladder and said fourth bladder form a distal bladder pair, and each of said proximate bladder pair and said distal bladder pair is configured to form pneumatic seals around said body portion during operation of the system.

45. A system for raising a core body temperature of a mammal, the system comprising:

a chamber for enclosing a body portion of a mammal;

a pneumatic seal in operative association with said chamber for sealing said chamber around said body portion and for inhibiting movement of said body portion relative to said chamber;

a thermal energy exchange system in operative association with said chamber, wherein said thermal energy exchange system comprises a heating element assembly coupled to a flexible membrane assembly, wherein said flexible membrane assembly enhances a transfer of heat from said heating element assembly to said body portion; and

a vacuum system operatively associated with said chamber while said thermal energy exchange system is in operation, wherein said vacuum system cyclically generates a selected sub-atmospheric pressure within said chamber.

46. The system of claim 45, wherein said body portion is one of an extremity, part of an extremity, a head, a neck, and a torso.

47. The system of claim 45, wherein said chamber comprises:

a base member;

a moveable member adapted to matingly engage said base member; and

a fastener adapted to maintain engagement of said base member with said moveable member.

48. The system of claim 45, wherein said chamber comprises:

a base member having a first distal end and a first sealing surface;

a moveable member having a second distal end pivotally mounted to said first distal end and a second sealing surface which reciprocably contacts said first sealing surface to enclose said body portion within said chamber.

49. The system of claim 48, further comprising a fastener in operative association with said base member and said moveable member for securely engaging said moveable member with said base member during operation of the system.

50. The system of claim 48, said flexible member assembly comprising a first flexible membrane associated with an interior surface of said moveable member and a second flexible membrane associated with an interior surface of said base member, wherein said first flexible membrane and said second flexible membrane are each configured to enhance surface contact between said heating element assembly and said body portion.

51. The system of claim 50, wherein said pneumatic seal comprises:

a first cuff positioned at a proximate end of said interior surface of said moveable member; and

a second cuff positioned at a proximate end of said interior surface of said base member;

wherein said first cuff and said second cuff are configured to surround said body portion when said moveable member contacts said base member to enclose said body portion within said chamber.

52. The system of claim 51, wherein said pneumatic seal further comprises:

a first bladder at least partially encased within said first cuff; and

a second bladder at least partially encased within said second cuff;

wherein said first bladder and said second bladder are configured to form a pneumatic seal around said body portion during operation of the system.

53. The system of claim 52, wherein said first bladder and said second bladder are operatively associated with a pressure system which provides positive pressure to expand said first bladder and said second bladder around said body portion during operation of the system.

54. The system of claim 48, wherein said heating element assembly further comprises:

a first heating element in association with said first flexible membrane; and

a second heating element in association with said second flexible membrane;

wherein said first heating element and said second heating element are adapted to enable a transfer of heat from each of said first heating element and said second heating element to said body portion; and

wherein said heat is transferred from said body portion to said thermal core of said mammal by a vascular system of said mammal.

55. The system of claim 54, wherein each of said first heating element and said second heating element is further adapted to enhance surface contact with said body portion.

56. The system of claim 54, wherein said first heating element and said second heating element are configured to generate a surface temperature of from about 37 °C to about 48 °C.

57. The system of claim 54, wherein said thermal energy exchange system further comprises at least one backing layer which is contiguous with at least one of said first heating element and said second heating element and contacts at least one of said first flexible membrane and said second flexible membrane.

58. The system of claim 57, wherein said at least one backing layer comprises an insulating material.

59. The system of claim 58, wherein said insulating material comprises a phase change material.

60. The system of claim 53, wherein said thermal energy exchange system further comprises:

a circulation pump;

a fluid reservoir in operative association with said circulation pump; and

a temperature regulator coupled to said fluid reservoir;

wherein said fluid reservoir is configured to store a heated fluid which is circulated by said circulation pump through said first heating element and said second heating element.

61. The system of claim 60, wherein each of said first heating element and said second heating element comprises a perfusion pad which is perfused with said heated fluid.

62. The system of claim 61, wherein said heated fluid is a liquid.

63. The system of claim 62, wherein said liquid is water.

64. The system of claim 45, wherein said chamber comprises:

a hollow tubular housing having an entry port positioned at a proximate end of said hollow tubular housing; and

wherein said flexible membrane assembly forms a continuous membrane within said hollow tubular housing and is adapted to envelop said body portion when said body portion is positioned within said chamber.

65. The system of claim 64, wherein said chamber further comprises an annular cuff in association with said entry port, said annular cuff adapted to surround said body portion when said body portion is positioned within said chamber.

66. The system of claim 65, wherein said annular cuff is further configured to inhibit movement of said body portion relative to said chamber when the system is in operation.

67. The system of claim 65, wherein said pneumatic seal further comprises a bladder at least partially encased within said annular cuff.

68. The system of claim 64, wherein said heating element assembly comprises a heating element that surrounds said body portion while positioned within said chamber.

69. The system of claim 68, wherein said heating element is configured to generate a surface temperature of from about 37 °C to about 48 °C.

70. The system of claim 68, wherein said thermal energy exchange system further comprises a backing layer which is contiguous with said heating element and said flexible membrane.

71. The system of claim 70, wherein said backing layer comprises an insulating material.

72. The system of claim 71, wherein said insulating material comprises a phase change material.

73. The system of claim 68, wherein said thermal energy exchange system further comprises:

a circulation pump;

a fluid reservoir in operative association with said circulation pump; and

a temperature regulator coupled to said fluid reservoir;

wherein said fluid reservoir is configured to contain a heated fluid which is circulated by said circulation pump through said heating element.

74. The system of claim 73, wherein said heating element comprises a perfusion pad which is configured to be perfused with said heated fluid.

75. The system of claim 45, wherein said selected sub-atmospheric pressure is from about -10 mmHg to about -400 mmHg, relative to atmospheric pressure.

76. The system of claim 75, wherein said vacuum system alternates between generating said selected sub-atmospheric pressure and permitting a return to atmospheric pressure within said chamber during operation of the system.

77. A system for lowering a core body temperature of a mammal, the system comprising:

a chamber for enclosing a body portion of a mammal;

a pneumatic seal in operative association with said chamber for sealing said chamber around said body portion and for inhibiting movement of said body portion relative to said chamber;

a thermal energy exchange system in operative association with said chamber, wherein said thermal energy exchange system comprises a cooling element assembly coupled to a flexible membrane assembly, wherein said flexible membrane assembly enhances a transfer of heat from said body portion to said cooling element assembly; and

a vacuum system operatively associated with said chamber while said thermal energy exchange system is in operation, wherein said vacuum system generates a selected sub-atmospheric pressure within said chamber.

78. The system of claim 77, wherein said body portion is one of an extremity, part of an extremity, a head, a neck, and a torso.

79. The system of claim 77, wherein said chamber comprises:

a base member;

a moveable member adapted to matingly engage said base member; and

a fastener adapted to maintain engagement of said base member with said moveable member.

80. The system of claim 77, wherein said chamber comprises:

a base member having a first distal end and a first sealing surface;

a moveable member having a second distal end pivotally mounted to said first distal end and a second sealing surface which reciprocably contacts said first sealing surface to enclose said body portion within said chamber.

81. The system of claim 80, further comprising a fastener in operative association with said base member and said moveable member for securely engaging said moveable member with said base member during operation of the system.

82. The system of claim 80, said flexible membrane assembly comprising a first flexible membrane associated with an interior surface of said moveable member and a second flexible membrane associated with an interior surface of said base member, wherein said first flexible membrane and said second flexible membrane are each configured to enhance surface contact between said energy element and said body portion.

83. The system of claim 82, wherein said pneumatic seal comprises:

a first cuff positioned at a proximate end of said interior surface of said moveable member; and

a second cuff positioned at a proximate end of said interior surface of said base member;

wherein said first cuff and said second cuff are configured to surround said body portion when said moveable member contacts said base member to enclose said body portion within said chamber.

84. The system of claim 83, wherein said pneumatic seal further comprises:

a first bladder at least partially encased within said first cuff; and

a second bladder at least partially encased within said second cuff.

wherein said first bladder and said second bladder are configured to form a pneumatic seal around said body portion during operation of the system.

85. The system of claim 84, wherein said first bladder and said second bladder are operatively associated with a pressure system which provides positive pressure to expand said first bladder and said second bladder around said body portion during operation of the system.

86. The system of claim 80, wherein said cooling element assembly comprises:

a first cooling element in association with said first flexible membrane; and

a second cooling element in association with said second flexible membrane;

wherein said first cooling element and said second cooling element are adapted to enable a transfer of heat from said body portion to each of said first energy element and said second energy element; and

wherein said heat is transferred from said thermal core of said mammal to said body portion by a vascular system of said mammal.

87. The system of claim 86, wherein each of said first cooling element and said second cooling element is further adapted to enhance surface contact with said body portion.

88. The system of claim 86, wherein each of said first cooling element and said second cooling element is configured to maintain a surface temperature of from about 5 °C to about 12 °C.

89. The system of claim 86, wherein said thermal energy exchange system further comprises:

a circulation pump;

a fluid reservoir in operative association with said circulation pump; and

a temperature regulator coupled to said fluid reservoir;

wherein said fluid reservoir is configured to contain a cooled fluid which is circulated by said circulation pump through said first cooling element and said second cooling element.

90. The system of claim 89, wherein each of said first cooling element and said second cooling element comprises a perfusion pad which is configured to be perfused with said cooled fluid.

91. The system of claim 90, wherein said cooled fluid is a liquid.

92. The system of claim 91, wherein said liquid is water.

93. The system of claim 77, wherein said chamber comprises:

a hollow tubular housing having an entry port positioned at a proximate end of said hollow tubular housing; and

wherein said flexible membrane assembly forms a continuous membrane within said hollow tubular housing and is adapted to envelop said body portion when said body portion is positioned within said chamber.

94. The system of claim 93, wherein said chamber further comprises an annular cuff in association with said entry port, said annular cuff adapted to surround said body portion when said body portion is positioned within said chamber.

95. The system of claim 94, wherein said annular cuff is further configured to inhibit movement of said body portion relative to said chamber when the system is in operation.

96. The system of claim 95, wherein said pneumatic seal further comprises a bladder at least partially encased within said annular cuff.

97. The system of claim 93, wherein said cooling element assembly comprises a cooling element that surrounds said body portion while positioned within said chamber.

98. The system of claim 97, wherein said cooling element is configured to maintain a surface temperature of from about 5 °C to about 12 °C.

99. The system of claim 97, wherein said thermal energy exchange system further comprises:

a circulation pump;

a fluid reservoir in operative association with said circulation pump; and

a temperature regulator coupled to said fluid reservoir;

wherein said fluid reservoir is configured to contain a cooled fluid which is circulated by said circulation pump through said cooling element.

100. The system of claim 99, wherein said cooling element comprises a perfusion pad which is configured to be perfused with said cooled fluid.

101. The system of claim 77, wherein said selected sub-atmospheric pressure is from about -10 mmHg to about -400 mmHg, relative to atmospheric pressure.

102. The system of claim 101, wherein said vacuum system alternates between generating said selected sub-atmospheric pressure and permitting a return to atmospheric pressure within said chamber during operation of the system.

103. A method for manipulating a core body temperature of a mammal, the method comprising the steps of:

enclosing a body portion of a mammal within a chamber;

sealing said chamber around said body portion and inhibiting movement of said body portion relative to said chamber;

generating a selected sub-atmospheric pressure within said chamber;

exposing said body portion to an energy element assembly; and

optimizing contact of said energy element assembly with said body portion via a flexible membrane assembly while generating said selected sub-atmospheric pressure to facilitate an exchange of thermal energy between said energy element assembly and a thermal core of said mammal.

104. The system of claim 103, wherein said body portion is one of an extremity, part of an extremity, a head, a neck, and a torso.

105. The method of claim 103, wherein sealing said chamber comprises creating a pneumatic seal around said body portion substantially without constricting blood flow to and from said body portion.

106. The method of claim 104, wherein creating a pneumatic seal further comprises activating a pressure system to expand at least one bladder to form a pressure cuff around said body portion.

107. The method of claim 104, wherein said chamber comprises a moveable member and a base member, and wherein sealing said chamber further comprises activating a fastening mechanism to seal a periphery of said moveable member to a periphery of said base member.

108. The method of claim 103, wherein generating a selected sub-atmospheric pressure comprises generating a pressure within said chamber of from about -10 mmHg to about –400 mmHg, relative to atmospheric pressure.

109. The method of claim 103, wherein generating a selected sub-atmospheric pressure comprises alternating between generating said selected sub-atmospheric pressure and permitting a return to atmospheric pressure within said chamber during operation of the system.

110. The method of claim 103, further comprising inserting said body portion within a sleeve prior to enclosing said body portion within said chamber.

111. The method of claim 103, wherein said energy element assembly comprises a heating element.

112. The method of claim 103, wherein said energy assembly comprises a cooling element.

113. A chamber for manipulating a core body temperature of a mammal, the chamber comprising:

a housing assembly configured to receive a body portion of a mammal;

a seal for sealing said housing assembly around said body portion and for inhibiting movement of said body portion relative to said housing assembly when the chamber is in operation;

an energy element assembly disposed within said housing assembly;

a flexible membrane assembly disposed proximate said energy element assembly; and

a vacuum assembly configured to effect a sub-atmospheric pressure within said housing assembly.

114. The chamber of claim 113, wherein said housing assembly comprises:

a base member;

a moveable member adapted to matingly engage said base member; and

a fastener adapted to maintain engagement of said base member with said moveable member.

115. The chamber of claim 113, wherein said housing assembly comprises a hollow tubular member having an entry port positioned at a proximate end of said hollow tubular member.

116. The chamber of claim 113, wherein said energy element comprises one of a heating element and a cooling element.

117. The chamber of claim 116, wherein said energy element comprises a perfusion pad which is configured to be perfused with a temperature-regulated fluid.

118. The chamber of claim 113, further comprising a backing layer which is disposed proximate said energy element.

119. The chamber of claim 118, wherein said backing layer comprises an insulating material.

120. The chamber of claim 119, wherein said insulating material comprises a phase change material.